UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OKLAHOMA

IN RE: GENENTECH HERCEPTIN (TRASTUZUMAB) MARKETING AND SALES PRACTICES LITIGATION	))))	**MDL DOCKET NO. 16-MD-2700 ALL CASES**

NON-PARTY PATHEON MANUFACTURING SERVICES LLC'S OPPOSITION TO PLAINTIFFS' MOTION TO COMPEL COMPLIANCE WITH SUBPOENA *DUCES TECUM*

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I. INTRODUCTION

Plaintiffs sent a document subpoena (the "Subpoena") to Patheon Manufacturing Services LLC ("Patheon") via certified mail and received by CT Corporation System, Raleigh, NC, on September 7, 2016. (See Plaintiffs' Motion to Compel Non-Party Patheon Manufacturing Services LLC to Comply with Subpoena *Duces Tecum* (the "Motion"), Ex. 1). By letter dated the same day (the "Sept. 7th Letter"), Plaintiffs advised Patheon that Genentech, Inc. ("Genentech") intended to file a Motion to Quash the Subpoena and that Patheon should stand down and not produce any documents until it received formal notice of the Court's ruling. (See Motion, Ex. 4). Based on that September 7th Letter, Patheon understandably believed it had no ability to do anything in response to the Subpoena; instead, Patheon had been directed to stand down and wait for the ruling on Genentech's Motion, which is exactly what it did.

Nine months later, Patheon received notice from Genentech's counsel that the Court denied the Motion to Quash and that Plaintiffs demanded Patheon produce documents responsive to the Subpoena. (See Certification of Christopher R. Carton ("Carton Cert."), ¶ 1). On June 20, counsel for Plaintiffs and counsel for Patheon participated in a meet-and-confer call to discuss the Subpoena. (See Carton Cert., ¶ 2). The parties engaged in a productive conversation and on June 26, Patheon sent Plaintiffs a letter committing to respond to the Subpoena the week of July 17. (See Motion, Ex. 2; Carton Cert., ¶ 3). Patheon also reasserted its position (the same position it took on the meet-and-confer call) that the fourteen (14) days permitted to object to the Subpoena began running the date Patheon received formal notice of the Court's denial of the Motion to Quash, which it did not receive until July 14. (See id.). On July 21, 2017, as agreed, Patheon responded to the Subpoena. (See Motion, Ex. 7). Patheon produced nearly 1,000 pages of documents (the "Production"), fully responsive to Requests One through Three of the

Subpoena. (See Motion, Ex. 7; Carton Cert., ¶ 6). The Production contained redactions; however, such redactions are permitted by Document No. 142: Stipulation and Order Regarding the Production of Electronically Stored Information and Hard Copy Documents. (See Carton Cert., ¶ 7). The Production was marked "Highly Confidential -- Attorneys' Eyes Only." Patheon will agree to remove the "Attorneys Eyes Only" designation, but will maintain the "Highly Confidential" designation, pursuant to the Protective Order entered in this case. Finally, Patheon objected to Request Number Four. Not only can Plaintiffs obtain documents responsive to that Request from Genentech -- the Defendant in the litigation -- but Genentech has already provided many (if not all) of those documents to Plaintiffs. (See Carton Cert., ¶ 9). Plaintiffs must simply look through Genentech's production. A non-party subpoena recipient should not be burdened with what will amount to a full-blown document production -- as if it were itself a party to the litigation -- if the party seeking the documents can obtain the same documents from an actual party to the litigation, in this case the defendant, Genentech.

Patheon did not receive a single email or call from Plaintiffs' counsel for nearly three weeks after sending him the Production. (See Carton Cert., ¶ 11). This prolonged lack-of-communication is significant in light of counsel's present urgency to receive more documents "immediately" (see Motion, Ex. 8, p. 2), and his filing a motion to compel just four business days after sending a deficiency letter. Further, counsel need only read the cover letter of the Production and flip a few pages to notice the redactions, attorneys-eyes-only designation, and non-response to Request Number Four. If there were any real urgency, he would have picked up the telephone and called Patheon's counsel immediately, as he has done in the past. Many of the objections could have been easily worked out and explained by a simple telephone call.

Patheon's August 9 letter demanding that Patheon "*immediately* supplement its production with the requested communications" was followed four days later by this Motion to Compel. (See Motion, Ex. 8, p. 2). Plaintiffs' counsel stated that he "attempted to reach Patheon's counsel by telephone" on two subsequent occasions. (See Motion, p. 1). However, he never sent a follow-up email nor did he reach out to Erica Mekles, the associate attorney working on this matter, who he spoke to several times since the meet-and-confer call. (See Carton Cert., ¶ 12). They even spoke on the telephone the week Patheon made the Production to discuss its content. (See id.). Plaintiffs' counsel did not make a good faith effort to meet and confer. In fact, he made a bad faith effort to do so. Based on the foregoing and below, the Court should deny Plaintiffs' Motion to Compel.

II. ARGUMENT

A. The Redactions are Proper Pursuant to Document No. 142: Stipulation and Order Regarding the Production of Electronically Stored Information and Hard Copy Documents.

The redactions are entirely permitted and justified. Pursuant to the Stipulation and Order Regarding the Production of Electronically Stored Information and Hard Copy Documents, "The parties may use redactions to protect attorney-client privilege, attorney work-product, any other applicable privilege or immunity, protected health information, other personal information, and non-responsive information regarding other unrelated products." (See Carton Cert., Ex. B, ¶ (I)(E)). Document No. 142 is applicable to non-parties: "This Production Stipulation and Order . . . governs the production of ESI and hard copy documents . . . , and specifies the form in which both parties *and non-parties* shall be required to produce Documents for use in the above-captioned case, and any actions that may be later consolidated with that case . . . ." (See id. at p.1, Introduction) (emphasis added). The redacted information in the Production includes

unrelated products, pricing, annual spend commitments, fees (handling, material and supply fees, component costs, termination or rescheduling fees), standards of care, limits of liability, remedies, performance metrics, market requirements, financial commitments, and capital expenditures. (See Carton Cert., ¶ 8). The redactions, most of which concern unrelated products, involve entirely unresponsive information. (See id.). The Court should deny Plaintiffs' request that Patheon produce unredacted documents or, at the very least, order an in-camera review of the Production.

B. ALL of the Documents Responsive to Request Number Four Can Be (or Have Been) Obtained from Genentech -- the Defendant in the Litigation; Patheon -- A Non-Party -- Should Not Be Burdened to Produce Those Same Documents.[1]

Federal Rule of Civil Procedure 45(d)(1) states that "[a] party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court must enforce this duty and impose an appropriate sanction — which may include lost earnings and reasonable attorney's fees — on a party who fails to comply." The Rule 45 "undue burden" standard requires sensitivity on the part of the court supervising discovery, in terms of the costs imposed on third parties. See Fed.R.Civ.P. 45(d)(2)(B) (any court order to compel compliance with a document subpoena shall "protect a person who is neither a party nor a party's officer from significant expense" of compliance). In addition, Federal Rule of Civil Procedure 26(b)(1)-(2) requires courts in "[a]ll discovery" to consider a number of factors potentially relevant to the question of undue burden, including but not limited to: whether the discovery is "unreasonably cumulative or duplicative" and whether the discovery sought is **"obtainable from some other source that is more**

[1] Patheon did not waive its ability to object to the Subpoena. Patheon did what it was told to do: stand down. Patheon received a letter from Plaintiffs' counsel directing it to take no further action until it received formal notice of the Court's decision on Genentech's Motion to Quash. Patheon acted reasonably in following the directive of the Sept. 7th Letter. The Court should not find waiver on such a technicality and under these misleading circumstances.

convenient, less burdensome, or less expensive." With these Rules, courts can adequately protect both the requesting party's right to evidence, and the responding party's right to the avoidance of unplanned risks, expenses, and logistical challenges.

Here, the documents Plaintiffs seek in Request Number Four are readily obtainable from defendant Genentech, a source that is more convenient, less burdensome and less expensive then production from non-party Patheon. Yet, Plaintiffs' counsel has taken no steps to limit undue burden and expense on Patheon, as Rule 45 requires. Plaintiffs seek from Patheon:

> All communications from Genentech, or a person or entity acting on its behalf, to Patheon Manufacturing Services about either (i) target fill weight for the harvested drug substance to be used in multi-dose vials of Herceptin, or (ii) target vial fill for multi-dose vials of Herceptin.

The Request is not limited in time.[2] Patheon's relationship with Genentech began more than seven years ago. If ordered to produce responsive documents, Patheon will be forced to drill down and find specific communications about specific topics in a relationship spanning the better part of a decade. As the Court is well-aware, with any electronic discovery, such a task necessitates developing a list of custodians, which will include anywhere from 30 to 50 people (many of whom have left the company), developing and testing search terms, running searches, document collection, document review, and document production. That process amounts to full-blown document discovery on a non-party, which is completely unwarranted given the existence of an alternative source for the same documents, which also happens to be a party to this litigation -- Genentech.

When asked during the meet-and-confer call why Plaintiffs could not obtain the documents from Genentech, counsel had no answer. Counsel simply admitted that he requested

[2] Rule 45 protections include temporal limitations. See Fed.R.Civ.P. 45(d)(3) ("[T]he court for the district where compliance is required must quash or modify a subpoena that . . . subjects a person to undue burden."). Subpoenas that have no temporal limitation should be quashed or modified to limit their breadth. (See id.).

the documents from Patheon "to check Genentech's discovery." (See Carton Cert., ¶ 4). In other words, his entire intent with request Number Four is to use non-party Patheon to make sure Genentech is complying with its own discovery obligations. A non-party subpoena cannot be used to check the discovery between two parties in a litigation. That "check" on party discovery is exactly the type of conduct Rule 45 seeks to prevent. The Court should not condone it.

Genentech necessarily maintains all communications between it and Patheon. Genentech is a party to the litigation, not Patheon. Thus, Plaintiffs can send the same request to Genentech and obtain the same communications it requests from Patheon. Further, Genentech has already produced Patheon documents regarding manufacturing processes for the Herceptin drug product, which would likely include target fill weights. Specifically, Genentech has produced "Prior Approval Supplement for Catalytica Pharmaceuticals, Inc. (now Patheon, Inc.) Drug Product Manufacturing Facility (as well as supplements/amendments to the Prior Approval Supplement). (See Carton Cert., ¶ 9(a)). The Prior Approval Supplement contains detailed information about the manufacturing processes for the Herceptin drug product, FDA-approved specifications for Herceptin, responses to questions posed by the FDA during its review, and certain correspondence with the FDA. (See id.). It has also produced Supply Agreements between Genentech and Patheon and Quality Agreements between Genentech and Patheon, which include Product Specific Requirements for Herceptin. (See id., ¶ 9(b),(c)). It has produced Annual Product Quality Reviews (which includes information related to Patheon) and Certificates of Analysis for lots of Herceptin 440 mg distributed in the United States since 2010 (including lots from Patheon), which show the specific protein content for each such lot. (See id., ¶ 9(d),(e)). Genentech will be producing reports of periodic audits of Patheon performed by Genentech." (See Carton Cert., ¶ 10).

Thus, Plaintiffs need look no further than Genentech's production, which is already in its hands, or request from Genentech -- first -- the communications between Genentech and Patheon it now seeks from Patheon. Only if, after conducting a complete document review of Genentech's production and serving the same request on Genentech that it now serves on Patheon, Plaintiffs come up empty, should Plaintiffs be permitted to demand those documents from Patheon. Such a process would comply with Rule 45's requirement that the attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on the party subject to the subpoena. Additionally, if Patheon is forced to respond to Request Number Four (at some point in the future), the Court should compel Plaintiffs to bear the expense related to production. Patheon will incur significant costs searching for and processing electronically stored information (ESI).

CONCLUSION

For the reasons set forth herein, Patheon respectfully requests that this Court deny Plaintiffs' Motion to Compel.

Dated: August 29, 2017

Respectfully submitted,

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